

510(k) Summary 260 Corvus Pie Medical

# 510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

#### **Submitter Information**

Colleen Hittle, Official Correspondent 8000 Castleway Drive Indianapolis, IN 46250

Phone:

(317) 849-1916

Facsimile:

(317) 5779070

Contact Person:

Colleen Hittle

Date:

October 18, 2000

807.92(a)(2)

Trade Name:

260 Corvus Ultrasound Imaging Systems

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulsed doppler imaging system
Ultrasonic pulsed echo imaging system

892.1550 892.1560

Classification Number:

90IYO

807.92(a)(3)

**Predicate Device(s)** 

Pie Medical

250

K915647

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

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510(k) Summary 260 Corvus Pie Medical

807.92(a)(5)

### **Device Description**

# Intended Use(s)

Pie Medical's 260 Corvus ultrasound systems used are to perform general diagnostic ultrasound studies under a physician's supervision including: abdominal, small organ, fetal, pediatric, peripheral vascular, intraoperative abdominal, musculoskeletal, cardiac, transrectal and transvaginal.

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510(k) Summary 260 Corvus Pie Medical

# Comparison Chart for Substantial Equivalence

	PIE 1150 (Predicate to 250, cleared via K900469)	PIE 250 (Predicate to 240, cleared via K915647	PIE 260Corvus To be added with this submission
Technology	Linear/Curved/ Mechanical Annular	Annular	Annular/Curved/Linear
Modes	B, B+M, M	B, B+B. B+M, M	B, B+B, B+M, M
Frequencies	3.5 – 7.5 MHz	3.5-7.5 MHz	3.5-8MHz
Applications	Abdominal/Fetal/ Pediatric/ Small organ/ Intraoperative	Abdominal / Small Organ/ Intraoperative/ Pediatric/ Peripheral Vascular/ Fetal	Abdominal/Small Organ/ Transvaginal/ Transrectal/ Intraoperative/Neonatal Cephalic/Pediatric/ Peripheral Vascular/ Fetal/Cardiac/ Musculoskeletal
Scan Converter	Full digital	Full digital	Full digital



JAN - 5 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Pie Medical c/o Ms. Colleen Hittle Official Correspondent The Anson Group 7992 Castleway Drive Indianapolis, Indiana 46250

Re: K003292

260 Corvus Ultrasound Imaging Systems

Dated: October 18, 2000 Received: October 20, 2000

Regulatory Class: II

21CFR §892.1560/Procode: 90 IYO 21CFR §892.1570/Procode: 90 ITX

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 260 Corvus Ultrasound Imaging Systems, as described in your premarket notification:

#### Transducer Model Number

401669 3.5/5.0 MHz Linear Array 410054 6.0/8.0 MHz Linear Array 402198 8.0 MHz Linear Array 401664 3.5/5.0 MHz Curved Array 401667 5.0/7.5 MHz Curved Array 401788 5.0/7.5 MHz Curved Array 402116 3.5/5.0 MHz Curved Array 402155 5.0/7.5 MHz Annular Array 402154 5.0/7.5 MHz Annular Array 402156 5.0/7.5 MHz Annular Array 402157 5.0/7.5 MHz Annular Array If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for

Daniel G. Schultz, M.D.

Saint a. Seren

Captain, USPHS

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices Office of Device Evaluation

Center for Devices and

Radiological Health

**Enclosures** 

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	f Operation			
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N				144 - 101		N	
Abdominal	<u> </u>	N	N		<u> </u>				N	- J 185, 205
Intraoperative Abdominal		N	N						.No.	
Intraoperative Neurological									1,000	
Pediatric	1	N	N					1	No. 2	e i e i grand dependent dest
Small Organ (specify)		N	N	<u> </u>					N	
Neonatal Cephalic	1	N	N						N	
Adult Cephalic	-	<del>                                     </del>							and agreement to be a transfer of the second	en e e e e e e e e e e e e e e e e e e
Cardiac	$\top$	N	N						N	and the second second
Tranesophageal	+	<b> </b>	<del>                                     </del>		<del>                                     </del>					
Transrectal		N	N						N	
Transvaginal		N	N						N	and the large section
Transurethral	+	-			-				No en considera	way . 1 - Consessi
Intravascular										zen i gaziotek
Peripheral Vascular	+	N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other							/	<u>, L</u>	1000	

N= new indication: P= previously cleared by FDA; E= added under Appendix E	Showid Ch. Segeron
14— new indication. 1— proviously clouded by 1.2.14.2. which	(Division Sign-Off)
Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)	Division of Reproductive, Abdominal, ENT.
Applicable combined modes: B+B; B+M	and Radiological Devices
Application continued income. 2-2, 2-1.	510(k) Number K003292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use	/
(Per 21 CFR 801	100)

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic										4.5		
Fetal		N	N	<b>_</b>					N			
Abdominal	· ·	N	N						N			
Intraoperative (specify)										a and the transition of the section		
Intraoperative Neurological												
Pediatric		N	N						N	site in the same of the same		
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic									Management of the state of the	00 WHEATS		
Cardiac									a to the constant of a	und in a special control of		
Tranesophageal									and Agrician			
Transrectal		1										
Transvaginal	+								and the state of t	gan i na tangan		
Transurethral									, neer	10.0003444		
Intravascular	+									a service a landy and a		
Peripheral Vascular										ura sustanti		
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other								<del>//</del>				
N= new indication: P=  Additional Comments:  Applicable combined in				DA; E= add	ded under A	appendix E	(Div Divi and	Radiologica	Off) roductive, Abo I Devices	dominal, EN		
						COVERN			K00326	-		
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Prescription Use \_\_\_\_\_ (Per 21 CFR 801.109)

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Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal	-	N	N		·				N		
Intraoperative Adominal		N	Ng taga	प्रकार १००	. HVA		·		N	ા ત્યાન સ્કાર્યાં મળવાના નવેસ	
Intraoperative Neurological				er Frankritaka <b>us</b>		e e e i jassassi	5.		0. 3744	1 - messtaress on	
Pediatric		N	N	1. 1.53,495	rvijtyrev.a.(a.s	i i jaka dangan	To the same say		N		
Small Organ (specify)		N	N						N	<u> </u>	
Neonatal Cephalic				· · · · · · (5 40)	in the Medical	of the rema	a introvers		Marin Andrew Company	er i de la compania	
Adult Cephalic	$\dagger$				n ranningsvirige	4 - 100, MAG	. <b>.</b>		gal et a letter og gette at	es al especitor	
Cardiac											
Tranesophageal	1				1 1 2 mg as 1990	N					
Transrectal	$\dagger$	<del>                                     </del>			~>				soft in the constant of the sound of the constant of the const	and a state of the	
Transvaginal									See Rest (See Control	salari i	
Transurethral									LONG THE SECTION OF T	gas in the contract sages	
Intravascular	1									James a second	
Peripheral Vascular		N	N						N		
Laparoscopic											
Musculo-skeletal Conventional		N	N		<b>†</b>				N		
Musculo-skeletal Superficial	1	N	N						И		
Other									a. Syra		

N= new indication: P= previously cleared by FDA; E= added under Appendix E	Danne Co. Symm
N= new indication: P= previously cleared by PDA, E= added under Appendix B	(Division Sign-Off)
Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)	Division of Reproductive, Abdominal, ENT,
Applicable combined modes: B+B; B+M	and Radiological Devices
Applicable combined modes. B. B. D. M.	510(k) Number <u>KDO 329</u> 2
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Concurrence of CDRH Office of Device Eval	uation (ODE)

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Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	<u> </u>									
Intraoperative Abdominal		N	N						N .:	a talah terdapat di dalah sebesah
Intraoperative Neurological										
Pediatric		N	N						L	t en degagaanted
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic	T								a i majah da menjar 14 ji mayarga Arb	a e e e e e e e e e e e e e e e e e e e
Cardiac				71.49	and or the contract			34,	and the second s	Mark Control of the Market
Tranesophageal				. Santak						
Transrectal										
Transvaginal				24.	a e e m				A Maria (Maria Maria)	under the state of the state of
Transurethral			1						1.1.25%	Mar en enganetina
Intravascular	-	1								vod
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other								Service !	1	

N= new indication: P=	previously cleared by FDA; E= added under Appendix E
Additional Comments:	Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes:

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number	00	3	24	12
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Concurrence of CDRH, Office of Device Evaluation (ODI	L)
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Prescription Use (Per 21 CFR 801.109)

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N						N		
Abdominal	-	N	N						N		
Intraoperative (specify)										et session of the supp	
Intraoperative Neurological											
Pediatric		N	N						mN - 250	g vog skila kjalega, sast	
Small Organ (specify)				-275401							
Neonatal Cephalic											
Adult Cephalic	<b>†</b>			and a set three	3 48				👁 varaga ta ayay sakeetikitii ka	50	
Cardiac				e consume Man	Lo view				ing the state of t	<b>an S</b> ala i Salaman (1987) (ili. sala	
Tranesophageal	-										
Transrectal	<del> </del>	<del>                                     </del>	<del>                                     </del>	Marine Charles	*	rd N.E.					
Transvaginal				<b>*</b> * * * * * * * * * * * * * * * * * *					us i nigo est	ayre wax year car	
Transurethral	1								restant stran - re	au Chair ann an	
Intravascular									- 9524		
Peripheral Vascular	-										
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial									`.	<u> </u>	
Other					<u></u>		<del></del>	4-1-	Legram		

N= new indication: P= previously cleared by FDA;	E= added under	Appendix E
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Additional Comments:

Applicable combined modes: B+B; B+M

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K603292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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	Mode of Operation										
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal		N	N						N	ters desired	
Intraoperative Abdominal		N	N						N	erinis de 1990 a	
Intraoperative Neurological										numer in the graduation	
Pediatric Pediatric		N	N						N		
Small Organ (specify)		N	N						N		
Neonatal Cephalic		N	N				-		m Mariner of the Salar	TELL TOWNS	
Adult Cephalic									stanting the state of the particular	a partition of the second of	
Cardiac											
Tranesophageal	1										
Transrectal	$\dagger$	<del>                                     </del>	1					Y's	# III. The between the	g se in a paper.	
Transvaginal									te the title title have to	sale o to a topotoce abo	
Transurethral	+								. 177-75-3871-553	- 2028	
Intravascular	1								n e the contraction of the	•	
Peripheral Vascular Laparoscopic		N	N						N		
	$\perp$		<u> </u>			1				ļ	
Musculo-skeletal Conventional										<u> </u>	
Musculo-skeletal Superficial								<u> </u>			
Other									a. Sym	<u></u>	

N= new indication: P= previously cleared by FDA; E= added under Appendix E	(Division Sign-Off)
	Division of Reproductive, Abdominal, ENT, and Radiological Devices
Applicable combined modes: B+B; B+M	510(k) Number <u>+ 603292</u>

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

#### Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					177	Mode o	f Operation			
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		.,,,								
Fetal										
Abdominal										লা গঢ় শব্দি হয়
Intraoperative (specify)									Car is majure	क्षेत्र । १८८८ वर्षा सङ्ग्रह सम्बद्धारी सङ्
Intraoperative Neurological									and a service	Fale Sylvapultiers
Pediatric		<u> </u>			<u> </u>	<u> </u>			darus is some s	a et et en gruppiglise au ven
Small Organ (specify) Neonatal Cephalic		N	N						N	e e e e e e e e e e e e e e e e e e e
_	<del> </del>		<u> </u>	<u> </u>				<del> </del>		
Adult Cephalic									na i seltura šanoveni	i se en tre hat water
Cardiac								,	en e	MAR HALLAND
Tranesophageal	-									
Transrectal	+	N	N		<u> </u>			-	N	
Transvaginal		N	N						N	กลุ่ม กระกรทรงสพาชา
Transurethral	+								na n	e er og er er en kallende
Intravascular										in and provide
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional	$\dagger$					1,20 <b>4</b>				
Musculo-skeletal Superficial										
Other									<u></u>	
N= new indication: P= Additional Comments: Applicable combined n	Small	Organs	(specifica				Divis	ision Sign-0	roductive, Abd	ominal, EN
							•	k) Number		292
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		(	Concurre	nce of CD	RH, Offic	e of Device E	Evaluation (OD	E)		

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#### Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal	-	N	N				<u>,                                      </u>		N	174. 0
Abdominal		N	N						N	
Intraoperative (specify)										, in the contract of the second s
Intraoperative Neurological										
Pediatric									anger i gart i mengger	er i nigeraa bed (*oors
Small Organ (specify)									and the second of the second o	into the too or the open of the
Neonatal Cephalic										
Adult Cephalic	1							,	and the second of the second second of the second second of the second s	. જેવા મુક્કેલ વક્ષુક્ <b>ર</b> ાફક
Cardiac									Marin the commence of the	t i jarinski utopero
Tranesophageal									Maskin	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Transrectal	1								Name of the second seco	
Transvaginal									MARINE TANAN SERVICE	to the second
Transurethral									sa s	*******
Intravascular									a,t P	a si sa sama
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional					مانيد د دور د					
Musculo-skeletai Superficial										
Other						<u> </u>		<del>1)</del>	2 1	1

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ther			
I= new indication: P= previously cleared by FDA; E= adde	xd under Appendix E	David a	
additional Comments:		(Division Sign-Off) Division of Reprodu	uctive, Abdominal, ENT,
Combined Mode: B + M		and Radiological De	evices * 003292
		510(k) Number	1,003212
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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	Г					Mode o	f Operation			
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Ophthalmic										
Fetal		N	N	1					N	15
Abdominal		N	N						N	
Intraoperative (specify)										n en
Intraoperative Neurological									general de la companya del la companya de la compan	a emiljes ve to in volve
Pediatric	_	N	N						N.	an er nærender
Small Organ (specify)		N	N						N	
Neonatal Cephalic		N	N						N	
Adult Cephalic		+							teal or a sufficient to and	sa s
Cardiac		1							and the second of the second o	والمعتادة فيتضمن والراريان والمعتادة
Tranesophageal	+	1	<del>-  </del>							
Transrectal		1								X4
Transvaginal									Goda (* 17. v. 17. Nerve w 1921) V	·
Transurethral									en marine	skyt in a strong to a strong
Intravascular										ngga a sa
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other								$A_{\prime}$	a Sign-Off)	

Other			<u></u>	
N= new indication: P=	previously clear	ed by FDA; E= a	dded under Appendix E	(Division Sign-Off)
Additional Comments:	Small Organs (	specifically, thyro	id, testicles and breast)	Division of Reproductive, Abdominal, ENT, and Radiological Devices
Applicable combined t	nodes: B+B; B+	М		510(k) Number <u>4003292</u>
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Ophthalmic										
								ļ		
Fetal		N	N						N	
Abdominal										
ntraoperative (specify)					·					in the leaves off the leave
Intraoperative Neurological									- Joseph	
Pediatric								<u> </u>	a a a a a a a a a a a a a a a a a a a	· · · · · · · · · · · · · · · · · · ·
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic									an in 15 nighta¥ytert	eri i kultur ya ya ili kulturi daleh
Cardiac									e programme de la companya del companya de la companya del companya de la company	AN WALLS TOKEN TO LEE
Tranesophageal	1									
Transrectal	1	1		<b>-</b>						
Transvaginal		N	N						N Street Company	kan terperatur terpedişeyi
Transurethral	-								- 6- 4- 6-	and the state of the state of
Intravascular	+									and special and the second
Peripheral Vascular			1				·			
Laparoscopic	1									
Musculo-skeletal Conventional	-	-								
Musculo-skeletal Superficial	1									
Other	士							1/		
N= new indication: P= Additional Comments: Applicable combined m	<u>Small</u>	Organs	(specifica				Divi and	Kadiologica	productive, Ab	dominal, EN
								k) Number		3292
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Prescription Use (Per 21 CFR 801.109)

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation										
Clinical Application	A	В	∲ M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
F												
Fetal												
Abdominal										- 10,436		
Intraoperative (specify)							·			of costs		
Intraoperative Neurological										The section of the second sections		
Pediatric								V 192.1	despt. Sim sy	2.00 g po		
Small Organ (specify)		N	N						N			
Neonatal Cephalic								ļ				
Adult Cephalic								eyestari <b>沙山</b>	, side is a compared that we	್ರ ಕೃತ್ವವಾಗಿ		
Cardiac								state destro	en juligare de promotere de la presidente	ter w Monday (1971), that is a		
Tranesophageal												
Transrectal		N	N						N			
Transvaginal								retreatur	et sindhelik tik in essel	an a sa s		
Transurethral									than a common section			
Intravascular									em	<b>14</b> (1) (1)		
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal			<del>                                     </del>									
Conventional					<u> </u>		_	<del>_</del>		-		
Musculo-skeletal												
Superficial		-			+			17		+		
Other								9/10	1/1/2			
N= new indication: P= Additional Comments:							Div	vision Sign- vision of Req	productive, Ab			
Applicable combined n	nodes:	B+B; E	9+M					l Radiologic (k) Number	1/	3292		
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Prescription Use \_\_\_\_\_\_\_\_(Per 21 CFR 801.109)

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

•					****	Mode o	f Operation			
Clinical-Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal	-	N	N						N	
Abdominal		N	N						N .	and the second
Intraoperative (specify)						T - Marships, res				a petak mining mengebahan
Intraoperative Neurological					·				32.00 - 32	N PANA TANGKA
Pediatric		N	N						»N	en estado en en proprieda
Small Organ (specify) Neonatal Cephalic										
Adult Cephalic	†								A CONTRACT OF	gent grature — kintika wa
Cardiac	1	N	N						N	
Tranesophageal			1		<b>†</b>					
Transrectal					<del> </del>					
Transvaginal									ee.	i Pagharos (1.93.98)
Transurethral	-	<u> </u>		-						
Intravascular		1								in and the second
Peripheral Vascular										11111
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other								(/	1	
N= new indication: P= Additional Comments: Applicable combined n				OA; E= add	led under A	ppendix E	. D	Division Signification of Tender of	Reproductive, gica: Devices	
								10(k) Numl		
(PLE	ASE D						ON ANOTHE		EEDED)	<del></del>
			Concurre	ence of CD	RH, Offic	e of Device I	Evaluation (OD	E)		

Prescription Use (Per 21 CFR 801.109)

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode o	f Operation			
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal										
Intraoperative (specify)									:	20
Intraoperative Neurological Pediatric										1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Small Organ (specify)	-	N	N						N	
Neonatal Cephalic										
Adult Cephalic									···	ya saka
Cardiac									age of the major of the control of t	reen - et suot ji valvetiigida e
Tranesophageal										
Transrectal										
Transvaginal	-	N	N						N	ngag
Transurethral										
Intravascular									·	
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other  N= new indication: P=  Additional Comments  Applicable combined	<u>Smal</u>	l Organ	s (specific				Div and	ivision Sign vision of Red Radiotogic O(k) Number	productive, A	
(PLF	ASE I	OO NOT	WRITE	BELOW.	THIS LINE	-CONTINUI	E ON ANOTHE	R PAGE IF N		
(1 0.			Concurr	ence of C	DRH, Offi	ce of Device	Evaluation (Ol	DE)		